

**ERRATA SHEET – ITEM 14**

**AUGUST 13, 2003**

**CALIFORNIA REGIONAL WATER QUALITY CONTROL BOARD  
SAN DIEGO REGION**

**TENTATIVE ORDER NO. R9-2003-0140  
NPDES PERMIT NO. CA0109193**

**WASTE DISCHARGE REQUIREMENTS  
FOR  
IDEC PHARMACEUTICALS CORPORATION  
NEW IDEC MANUFACTURING OPERATIONS (NIMO)  
SAN DIEGO COUNTY**

The following changes to Fact Sheet and tentative Order No. R9-2003-0140 reflect adjustments to address comments submitted to the Regional Board by interested persons. The deleted text is shown as *strikethrough*; added text is shown as *underlined*.

**1. FACT SHEET**

***a. page 1, paragraph 1 (Section 1 - Contact Information) of Fact Sheet***

IDEC Pharmaceuticals Corp. Contact Person:

Joe Hess  
Manager, Environmental Health and Safety  
~~(858) 431-8229~~  
~~3010 Science Park Road~~  
~~San Diego, CA 92191~~  
(858) 431-8500  
3030 Callan Road  
San Diego, CA 92121  
Email: [jhess@idecpharm.com](mailto:jhess@idecpharm.com)

***b. page 2, paragraph 4 (Section 3.A - Facility Site) of Fact Sheet***

~~IDEC's NIMO site is located on approximately 90 acres on a parcel located on the east side of Corporate Center Drive between Ocean Ranch Parkway and Avenida De La Plata in the Ocean Ranch Corporate Center (see Attachment 1 for facility location map). IDEC owns approximately 90 acres of land in a parcel located on the east side of Corporate Center Drive between Ocean Ranch Parkway and Avenida De La Plata in the Ocean Ranch Corporate Center (see Attachment 1 for facility location map). The NIMO facility will be developed on approximately 45 acres of this land.~~ The NIMO facility is a multi-product, biopharmaceutical manufacturing complex with 500,000 square feet of building space. The complex will consist of five buildings: manufacturing building, laboratory, office, utility building, and warehouse operations building. The manufacturing building will contain three seed trains, six fermenters, two harvest suites, and

one purification suite for simultaneous production of ~~the two main products Rituxin® and ZEVALIN™~~ monoclonal antibodies for cancer and autoimmune diseases (see Attachment 2 for facility layout diagram).

***c. page 3, paragraph 4 (Section 3.B - Biologics Manufacturing Process) of Fact Sheet***

Formulation is the final step in the drug substance manufacturing process. The primary objective of the formulation process is to dilute the drug substance into the final carrier solution. Following formulation, the purified product is held as a bulk liquid until such time that it is filled into sealed vials that will be delivered to the point of use. The bulk liquid final fill operations into vials will not be conducted at the NIMO facility. These fill operations will be conducted at an offsite location.

***d. page 4, paragraph 2 (Section 4.A(1) - Primary City Water Treatment) of Fact Sheet***

The sources of wastewater generated from the primary City water treatment include backwashing and rinsing of the triplex multimedia filter (MMF) and triplex softener unit serving the primary city water treatment train. A brine waste is also generated from the regeneration of the softener resin with a concentrated brine solution. A total of approximately 26,000 gpd of wastewater will be generated from the backwashing and rinsing of the MMF. A total of approximately 27,000 gpd of brine and wastewater will be generated from the triplex softener unit backwashing, softener regeneration, and rinsing processes. IDEC has submitted softener regenerate waste brine test data for representative sampling conducted at its ~~San Diego (Torreyana) facility~~ NICO facility in Oceanside. The water purification and softening processes and associated discharges at the ~~Torreyana facility~~ NICO facility are similar to the NIMO site.

***e. page 5, paragraph 2 (Section 4.A(2) – Pretreatment of Water for Injection) of Fact Sheet***

The sources of wastewater generated from the *Water for Injection* (WFI) pretreatment system include backwashing and rinsing of the simplex carbon filter and softener units serving the WFI pretreatment train and from the regeneration of the softener resin with a concentrated brine solution. The wastewater flow from the WFI includes 9,500 gpd from the softening units and 2,250 gpd from the carbon filters. The pollutants contained in the brine generated from the WFI pretreatment system are similar to those found in the brine from the primary City water treatment system. The pollutants include sodium, calcium, magnesium, and other salts. A small amount of sulfuric acid (20% solution) will be added to one of the simplex softener units associated with the WFI. The acid will be used to maintain the pH of the softener effluent in the 7 to 8.3 range. This range of pH will ensure proper functioning of the WFI vapor compression stills.

***f. page 6, paragraph 2 (Section 4.A(5) - Combined Discharge Characterization) of Fact Sheet***

The 155,000 gpd (maximum flow rate) of discharge from the NIMO facility, covered under Tentative Order No. R9-2003-0140, will be a combination of the waste brine (softener regeneration brine, filter and softener backwash/rinse waters), cooling tower/boiler/compression stills blowdown discharges, and clean steam generator test flows. IDEC has provided representative data for softener regenerate waste brine sampling conducted at its ~~San Diego (Torreyana) facility~~ existing NICO facility in Oceanside (see *Section 4.A.(1)*) of Fact Sheet).

***g. page 8, paragraph 2 (Section 4.D - Stormwater Discharges) of Fact Sheet***

~~On August 16, 2002, the SWRCB processed IDEC's Notice of Intent (NOI) to comply with the Statewide General Industrial Storm Water Permit and assigned the NIMO site with a WDID identification number of 937I017431. IDEC will be submitting a Notice of Intent (NOI) to comply with the Statewide General Industrial Storm Water Permit once construction of the NIMO facility is completed.~~ Pursuant to the General Permit, IDEC will have to prepare a *Storm Water Pollution Prevention Plan* (SWPPP) to minimize pollutants in storm water runoff from the site. The overall objectives of the SWPPP are to identify sources of pollution that effect the quality of industrial storm water discharges and authorized non-storm water discharges, and implement *Best Management Practices* (BMPs) to reduce or prevent pollutants in storm water discharges.

**2. TENTATIVE ORDER NO. R9-2003-0140**

***a. page 6, Finding 17 of Tentative Order No. R9-2003-0140***

Storm water discharges associated with industrial activities from IDEC's NIMO site will be regulated pursuant to the *Statewide General Industrial Storm Water Permit* (SWRCB Water Quality Order No. 97-03-DWQ NPDES General Permit No. CAS000001, *Waste Discharge Requirements for Storm Water Associated with Industrial Activities Excluding Construction Activities*, April 17, 1997). ~~The NIMO site has been assigned a WDID identification number of 937I017431.~~

***b. page 18, Section F.5 (Notifications) of Tentative Order No. R9-2003-0140***

Storm water discharges associated with industrial activities from IDEC's NIMO site will be regulated pursuant to the *Statewide General Industrial Storm Water Permit* (currently Order No. 97-03-DWQ NPDES General Permit No. CAS000001, *Waste Discharge Requirements for Storm Water Associated with Industrial Activities Excluding Construction Activities*, April 17, 1997). ~~The NIMO site has been assigned a WDID identification number of 937I017431.~~

Errata Sheet – Item 14  
Tentative Order No. R9-2003-0140  
IDEC Pharmaceuticals Corporation (NIMO Facility)

-4-

August 13, 2003

